

REMARKS

Applicant thanks the Examiner for the very thorough consideration given the present application.

Claims 2-6 are now present in this application. Claims 2 and 4-6 are independent.

Claims 4-6 have been added. No new matter is involved. Reconsideration of this application, as amended, is respectfully requested.

I. Priority Under 35 U.S.C. § 119

The Examiner still has not acknowledged Applicant's claim for foreign priority under 35 U.S.C. §119, and receipt of the certified priority document. Acknowledgment thereof by the Examiner in the next Office Action is again respectfully requested.

II. Rejections Under 35 U.S.C. § 103

Claims 2 and 3 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,571,127 to DeCampli in view of U.S. Patent 5,344,424 to Roberts et al. ("Roberts") and further in view of U.S. Patent 5,599,351 to Haber et al. ("Haber"). This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Because the rejection is based on 35 U.S.C. §103, what is in issue in such a rejection is "the invention as a whole," not just a few features of the claimed invention. Under 35 U.S.C. §103, " [a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. See In re O'Farrell, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. See Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. §103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. See, In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the

pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. F-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. Note, In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Eritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A showing of a suggestion, teaching, or motivation to combine the prior art references is an “essential evidentiary component of an obviousness holding.” C.R. Bard, Inc. v. M3 Sys. Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not “evidence.” See In re Dembiczak, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Moreover, it is well settled that the Office must provide objective evidence of the basis used in a prior art rejection. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. See, In re Lee, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Furthermore, during patent examination, the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the Applicant is entitled to the patent. Only when a *prima facie* case is made, the burden shifts to the applicant to come forward to rebut such a case.

DeCampli discloses a scalpel having a retractable U-shaped blade carrier 40 with a blade-receiving portion 23 to receive standard scalpel blades 50.

DeCampli distinguishes his scalpel from prior art scalpels such as, for example, scalpels that “do not even contemplate blade replacement, thus requiring a surgeon to have available and use several scalpels during the course of a single operation, at considerably higher cost than that of replacement blades alone (col. 1, lines 43-50),” and expressly discloses that its scalpel uses removable and replaceable blades. DeCampli also distinguishes its device from disposable scalpels which use “multiple internal components, including buttons, springs, etc.,” indicating that “such complicated designs may lead to unreliability, and high manufacture and assembly costs” and “may increase dramatically the effort to disassemble the devices to ensure adequate cleaning and sterilization.” See col. 2, lines 21-30, for example.

DeCampli locks the blade and blade carrier in the two different positions (extended and retracted) using a single engagement block 43 that fits either into an engagement hole 34 adjacent one end of the handle portion 21 or in a separate engagement hole adjacent the opposite end of the handle portion 21. A single tab or button 27 is connected to the engagement block 43 to depress the engagement block and disengage the engagement block from an engagement hole.

A fair, balanced reading of DeCampli, including the paragraph bridging columns 5 and 6, reveals that the DeCampli scalpels are purposefully designed to accept conventional scalpel blades 50 and, in this regard, all disclosed

embodiments are provided with a blade carrier 40 that is a separate element shaped to accept conventional scalpel blades 50. In fact, as pointed out above, DeCampli specifically distinguishes its scalpels from prior art scalpels where the blades do not permit blade replacement.

The Office Action fails to discuss these explicitly disclosed characteristics of DeCampli.

Instead, the Office Action merely concludes that it would be obvious to one of ordinary skill in the art to modify DeCampli "by having the blade integrally fixed to the blade-fixing member in view of Roberts" which teaches a surgical scalpel with a blade that is integrally fixed to its blade fixing member "to eliminate connection between the blade and blade-fixing member."

Applicant does not understand this rejection in the sense that DeCampli will always have a connection between its blade and its blade-fixing member regardless of whether they are made of separate elements or a single element. Moreover, because DeCampli explicitly teaches using an integral scalpel blade and blade holder, the blade clearly fitting onto the blade holder as shown, for example, in Fig. 3 and described, for example, in col. 4, lines 35-44, Applicant does not why the Roberts reference is being applied, at all. In this regard, clarification is requested

Moreover, the Office Action fails to provide proper motivation for one of ordinary skill in the art to modify DeCampli in view of Roberts. Furthermore, the

statement given to justify making the proposed modification of DeCampli in view of Roberts, i.e., “to eliminate connection between the blade and the blade-fixing member” is not a statement of motivation but is merely a statement of what will result when the blade and blade holder are made in a single piece. Accordingly, the Office Action fails to provide any motivation to make the proposed modification of DeCampli or explain what that modification is with respect to the claimed invention.

Thus, the Office Action has not made out a *prima facie* case of proper motivation to modify DeCampli to redesign DeCampli because of the lack of a proper statement of why one of ordinary skill in the art would be motivated to modify DeCampli, as suggested.

Moreover, even if this proposed modification were made to DeCampli, it would not result in, or render obvious the claimed invention.

In this regard, the Office Action admits that DeCampli, as proposed-to-be-modified in view of Roberts, does not disclose “the second fixing projection.”

In an attempt to remedy this deficiency, the Office Action turns to Haber. The Office Action concludes that it would be obvious to further modify DeCampli “by having a second fixing projection interlocked with the second fixing groove in view of Haber to provide an interlocking means when the blade member is retracted into the blade enclosing member.”

The Office Action does not accurately or fully describe Haber or address the fundamental significant differences between these references.

The Office Action states that Fig. 5 of Haber discloses a scalpel “comprising a blade fixing member (S3D3) having a first fixing projection 114 interlocked with the first fixing groove 108 and a second fixing projection 122 interlocked with the second fixing groove 104” (emphasis added).

In actuality, Haber discloses two distinctly different and separate locking stop elements. One locking stop element is locking detent stop 122 that is part of slider/blade holder S3 and that fits into locking detent window 104 of the sheath. The other locking stop element is detent D3, which is a completely separate and distinct element than slider S3, and has “extension graspers 114” that can penetrate into blade extension windows 108 (col. 5, lines 46-61, for example) of the sheath.

A user never touches slider S3 in operating Haber’s scalpel, and only touches detent D3 to operate the scalpel. Moreover, the extension graspers 114 of Haber’s detent D3 serve only to lock the scalpel in a blade-extended position (col. 5, lines 35-63). Haber’s detent D3 has no element that locks the scalpel in the sheathed position.

Only Haber’s slider/blade holder S3 has detent stop 122 to lock itself and the scalpel in a fully retractable, and non-releasable position.

Furthermore, the Office Action never explains why one of ordinary skill in the art would be motivated to modify DeCampli's single tab/button into a two projection tab/button, or exactly how such a two projection tab/button will work with DeCampli's slots provide a workable device, when DeCampli's device apparently works well in its present form.

Nor does the Office Action explain why one would go to the trouble and expense of providing two fixing projections in DeCampli, when such a construction would probably be more costly and complicated to manufacture and use and when DeCampli's single projection appears to work well. Additionally, Haber's detent D3 is located on the broad flat side of the scalpel sheath whereas DeCampli's single projection is located on the narrow side edge of the scalpel sheath.

Moreover, because Haber provides his second detent on an element separate and distinct from its slider, one would logically have to provide the proposed second projection separate and apart from DeCampli's slider and that would require a complete redesign of DeCampli, as would the orientation of the finger-contacting detents, which one of ordinary skill in the art would have no incentive to do, and would require further invention.

Applicants respectfully submit that Haber is so fundamentally different in construction and method of operation than DeCampli that one of ordinary skill in the art would not know where to begin to modify DeCampli in view of Haber,

and the Office Action certainly fails to provide any guidance as to exactly how DeCampli's single tab/detent and single engagement block is to be modified to achieve a workable device in any manner, let alone in a manner that would provide motivation to modify the eminently workable and simple engagement/locking mechanism of DeCampli. Further, in this regard, the Office Action fails to discuss the spring biasing mechanism feature in Haber, which is a feature of scalpels that is distinguished over by DeCampli, as pointed out above

A fair, balanced view of the proposed rejection reveals that it is based completely on hindsight reconstruction of Applicant's invention based solely on Applicant's disclosure, fails to provide a *prima facie* showing of proper motivation to modify DeCampli as suggested because of (1) the failure of the Office Action to provide motivation to modify the primary reference in view of the secondary references, (2) the failure of DeCampli to need to be modified to achieve an integral blade and blade-holder feature (3) the significant fundamental differences between applied references, including the locking detent features of the applied references, (4) the apparent proper workability of DeCampli that needs no modification to work properly and efficiently, and (5) the complete absence of explanatory details in the Office Action of what the proposed modification of DeCampli will look like and how it will operate, leaving such details to further invention.

Accordingly, reconsideration and withdrawal of this rejection of claims 2-3 is respectfully requested.

III. New Claims 4-6

Claims 4-6 have been added for the Examiner's consideration.

Claim 4 recites the subcombination of a handle for a surgical scalpel having the handle features recited in claim 3. Support for this subject matter is found in claim 3.

Claim 5 recites the subcombination of a blade-fixing member for a scalpel having the features recited in claim 2. Support for this subject matter is found in claim 2.

Claim 6 recites a disposable surgical scalpel with the features of claims 1 and 3. Support for this subject matter is found in originally filed claim 1 (now canceled) and claim 3.

Claims 4-6 are believed to be allowable for the reasons that claims 2 and 3 are allowable, as discussed above.

IV. Additional Cited References

Because the remaining references cited by the Examiner have not been utilized to reject the claims, but have merely been cited to show the state of the art, no comment need be made with respect thereto.

V. Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46,472, at (703) 205-8076, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit

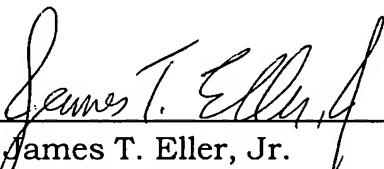
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Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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